Appl. No. 09/516,078 Amdt. Dated March 16, 2004 Reply to Office action of September 16, 2003

## Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

## **Listing of Claims:**

Claims 1-6 (canceled).

Claim 7 (currently amended): The A suppository based vaccine—delivery system of claim 6 for induction of an immune response, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly-expressed and combinations thereof, that comprises nucleic acids, proteins, lipids, or combinations thereof capable of producing humoral- or cellular-mediated immunity in humans or animals; and

(b) a suppository base comprising polyethylene glycol or a combination of polyethylene glycol and polysorbate;

wherein the suppository is adapted to be inserted into the anorectal or urogenital orifice of a human or animal so as to allow the suppository to be in contact with tissues of the anorectal or urogenital orifice to facilitate transfer of suppository material therethrough, and

wherein the polyethylene glycol suppository basesaid combination is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate.

Claims 8-11 (canceled).

Claim 12 (currently amended): A suppository-based vaccine—delivery system for prophylaxis—against—urogenitally or anorectally transmitted infections in humans or animals induction of an immune response, said suppository comprising:

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- (a) a vaccine or vaccine adjuvant(s) comprising purified, mutated, synthetic or genetically engineered constituents of known pathogens of urogenital pathogens, anorectal pathogens and combinations thereof; and
- (b) a suppository base, selected from the group consisting of comprising polyethylene glycol, polysorbate and or a combinations thereof of polyethylene glycol and polysorbate;

wherein the polyethylene glycol suppository basesaid combination is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about 950 to about 3700, and wherein the suppository comprises from about 50% to greater than 99% by weight of the suppository base; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine adjuvant(s) material therethrough.

Claim 13 (currently amended): A suppository-based vaccine delivery system for prophylaxis against genitourinary or anorectal tract infections in humans or animals induction of an immune response, said suppository resulting from the mixture of:

- (a) a vaccine or vaccine adjuvant comprising whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that comprises nucleic acids, proteins, lipids, or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and
- (b) a suppository base, selected from the group consisting of comprising polyethylene glycol, polysorbate and or a combinations thereofof polyethylene glycol and polysorbate;

wherein the polyethylene glycol suppository basesaid combination is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to

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about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about 950 to about 3700, and wherein the suppository comprises from about 50% to greater than 99% by weight of the suppository base; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine or vaccine adjuvant(s) material therethrough.

Claims 14-17 (canceled).

Claim 18 (currently amended): The A method of claim 17 for producing an immune response in humans or animals, said method comprising the steps of:

(a) inserting a suppository into an anorectal or urogenital orifice of a human or animal, wherein said suppository comprises a vaccine or vaccine adjuvant(s) material comprised of whole, fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that comprises nucleic acids, proteins, or combinations thereof capable of producing humoral or cellular-mediated immunity against urogenital or anorectal disease in humans or animals and a suppository base, wherein the suppository base comprises polyethylene glycol or a combination of polyethylene glycol and polysorbate; and

the anorectal or urogenital orifice to facilitate transfer of the vaccine or vaccine adjuvant material therethrough and induce an immune response in the human or animal, and

wherein the suppository basesaid combination is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate.

Claims 19-20 (canceled).